IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	
Michael E. JUNG et al.	Art Unit: 1614
Appl. No. 10/590,445	Examiner: Savitha M. Rao
Confirmation No. 6734	Atty. Docket No. 58086-235854
Filed: August 24, 2006	
For: METHODS AND MATERIALS FOR ASSESSING PROSTATE CANCER THERAPIES AND COMPOUNDS	Customer No. 26694 PATENT TRADEMARK OFFICE

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

I, the undersigned, hereby declare the following, based on my own knowledge, information, and belief:

1. I am an inventor of subject matter described and claimed in the above-identified U.S. patent application bearing serial number 10/590,445.

2. I am a Distinguished Professor in the Department of Chemistry at the University of California, Los Angeles. I hold the degree of Doctor of Philosophy in the field of Organic Chemistry from Columbia University. I have received numerous awards including the American

Chemical Society Arthur C. Cope Scholar Award and Glenn T. Seaborg Award. I am the author or coauthor of over 265 scientific publications. My group conducts research in topics including the development of new synthetic methods, the total synthesis of biologically active natural products, and medicinal chemistry. I serve as a consultant to numerous pharmaceutical companies, ranging from start-ups to Fortune 500 companies.

3. The 4-[3-(azidophenyl)-4,4-dimethyl-5-oxo-2-thioxoimidazolidin-1-yl]-2-trifluoromethylbenzonitrile compound was found to exhibit strong antagonistic effects on the ligand binding domain of the androgen receptor, did not exhibit agonistic effects, and inhibited the growth of the cells of the LNCaP hormone-refractory prostate cancer cell line. These results were surprising and unexpected.

4. Small changes in the structure of a compound can have large and unpredictable effects on the medicinal activity of the compound. For example, the attached drawing compares the activity of the compound RU 59063, having a dimethyl group and a butanol group pendant from a hydantoin ring, with the compound RD37, having a cyclobutyl ring and a methylphenyl group pendant from the hydantoin ring. The RD37 compound was more effective in suppressing the expression of prostate specific antigen (PSA) by hormone-refractory prostate cancer cells (LNCaP) than was the RU 59063 compound. One of ordinary skill in the art would not have been able to predict the activity of a compound having a phenyl group directly bonded to a nitrogen of a hydantoin ring based on observations made with a compound having a non-aromatic group bonded to the nitrogen of the hydantoin ring.

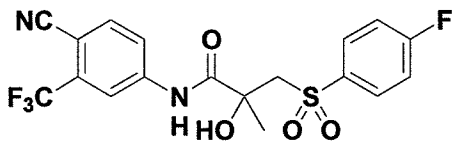
5. A number of factors lead one of skill in the medicinal chemistry art away from adding an azide group to a chemical compound for the purpose of developing a medicinal compound. For example, photoreactivity of the azide group can result in such a medicinal compound having a short shelf life. Furthermore, the azide group can react with reducing agents in cells, so that the azide functionalized compound can have a short half-life in the body of a subject or patient and/or induce unwanted side effects. Medicinal compounds having an azide group are rare. A finding that a particular compound or limited class of compounds having an azide group is useful in a specific medicinal context would not lead one of skill in the art to attempt the substitution of an azide group on structurally different compounds or classes of compounds for medicinal purposes.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

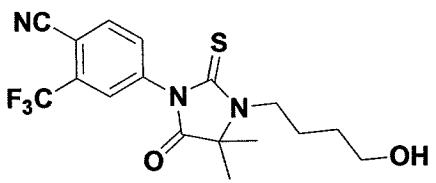
Signed this 25th day of August, 2009

Michael E. Jung, Ph.D.

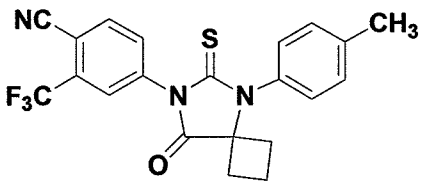
DC2/1052764



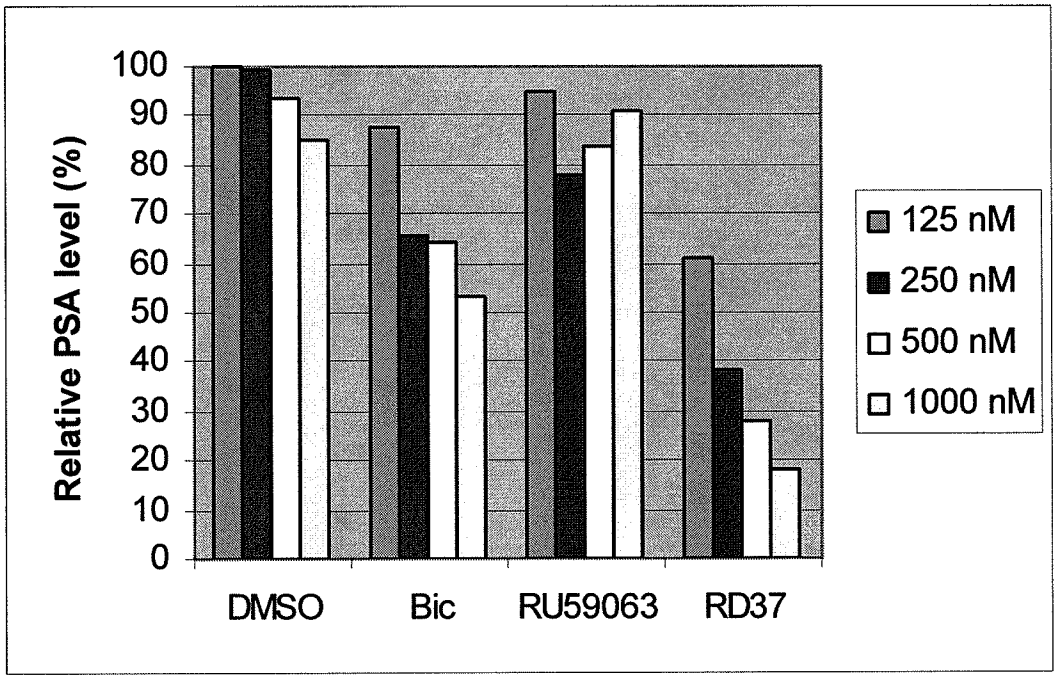
Bicalutamide



RU 59063



RD37



Parental LNCap cells (FBS media)